

standards, and procedures for the system's use.

Inspector. Any employee of the Animal and Plant Health Inspection Service or other person authorized by the Administrator to inspect and certify the plant health status of plants and products under this part.

§ 305.2 Irradiation treatment of imported fruits and vegetables for certain fruit flies and mango seed weevils.

(a) *Approved doses.* Irradiation at the following doses for the specified fruit flies and seed weevils, carried out in accordance with the provisions of this section, is approved as a treatment for all fruits and vegetables:

IRRADIATION FOR FRUIT FLIES AND SEED WEEVILS IN IMPORTED FRUITS AND VEGETABLES

Scientific name	Common name	Dose (gray)
(1) <i>Bactrocera dorsalis</i>	Oriental fruit fly	250
(2) <i>Ceratitis capitata</i>	Mediterranean fruit fly	225
(3) <i>Bactrocera cucurbitae</i>	Melon fly	210
(4) <i>Anastrepha fraterculus</i>	South American fruit fly	150
(5) <i>Anastrepha suspensa</i>	Caribbean fruit fly	150
(6) <i>Anastrepha ludens</i>	Mexican fruit fly	150
(7) <i>Anastrepha obliqua</i>	West Indian fruit fly	150
(8) <i>Anastrepha serpentina</i>	Sapote fruit fly	150
(9) <i>Bactrocera tryoni</i>	Queensland fruit fly	150
(10) <i>Bactrocera jarvisi</i>	(No common name)	150
(11) <i>Bactrocera latifrons</i>	Malaysian fruit fly	150
(12) <i>Sternochetus mangiferae</i> (Fabricus)	Mango seed weevil	300

(b) *Location of facilities.* Where certified irradiation facilities are available, an approved irradiation treatment may be conducted for any fruit or vegetable either prior to shipment to the United States or in the United States. Irradiation facilities certified under this section may be located in any State on the mainland United States except Alabama, Arizona, California, Florida, Georgia¹, Kentucky, Louisiana, Mississippi¹, Nevada, New Mexico, North Carolina¹, South Caro-

lina, Tennessee, Texas, and Virginia. Prior to treatment, the fruits and vegetables to be irradiated may not move into or through any of the States listed in this paragraph, except that movement is allowed through Dallas/Fort Worth, Texas, as an authorized stop for air cargo, or as a transloading location for shipments that arrive by air but that are subsequently transloaded into trucks for overland movement from Dallas/Fort Worth into an authorized State by the shortest route.

(c) *Compliance agreement with importers and facility operators for irradiation in the United States.* If irradiation is conducted in the United States, both the importer and the operator of the irradiation facility must sign compliance agreements with the Administrator. In the facility compliance agreement, the facility operator must agree to comply with any additional requirements found necessary by the Administrator to prevent the escape, prior to irradiation, of any fruit flies that may be associated with the articles to be irradiated. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by the Administrator to ensure the shipment is not diverted to a destination

¹Irradiation facilities may be located at the maritime ports of Gulfport, MS, or Wilmington, NC, or the airport of Atlanta, GA, if the following special conditions are met: The articles to be irradiated must be imported packaged in accordance with paragraph (g)(2)(i)(A) of this section; the irradiation facility and APHIS must agree in advance on the route by which shipments are allowed to move between the vessel on which they arrive and the irradiation facility; untreated articles may not be removed from their packaging prior to treatment under any circumstances; blacklight or sticky paper must be used within the irradiation facility, and other trapping methods, including Jackson/methyl eugenol and McPhail traps, must be used within the 4 square miles surrounding the facility; and the facility must have contingency plans, approved by APHIS, for safely destroying or disposing of fruit.

other than treatment and to prevent escape of plant pests from the articles to be irradiated during their transit from the port of first arrival to the irradiation facility in the United States.

(d) *Compliance agreement with irradiation facilities outside the United States.* If irradiation is conducted outside the United States, the operator of the irradiation facility must sign a compliance agreement with the Administrator and the plant protection service of the country in which the facility is located. In this agreement, the facility operator must agree to comply with the requirements of this section, and the plant protection service of the country in which the facility is located must agree to monitor that compliance and to inform the Administrator of any noncompliance.

(e) *Certified facility.* The irradiation treatment facility must be certified by the Administrator. Recertification is required in the event of an increase or decrease in the amount of radioisotope, a major modification to equipment that affects the delivered dose, or a change in the owner or managing entity of the facility. Recertification also may be required in cases where a significant variance in dose delivery has been measured by the dosimetry system. In order to be certified, a facility must:

(1) Be capable of administering the minimum absorbed ionizing radiation doses specified in paragraph (a) of this section to the fruits and vegetables;²

(2) Be constructed so as to provide physically separate locations for treated and untreated fruits and vegetables, except that fruits and vegetables traveling by conveyor directly into the irradiation chamber may pass through an area that would otherwise be separated. The locations must be separated by a permanent physical barrier such as a wall or chain link fence 6 or more feet high to prevent transfer of cartons, or some other means approved during certification to prevent re-infestation of articles and spread of pests;

²The maximum absorbed ionizing radiation dose and the irradiation of food is regulated by the Food and Drug Administration under 21 CFR part 179.

(3) If the facility is located in the United States, the facility will only be certified if the Administrator determines that regulated articles will be safely transported to the facility from the port of arrival without significant risk that plant pests will escape in transit or while the regulated articles are at the facility.

(f) *Monitoring and interagency agreements.* Treatment must be monitored by an inspector. This monitoring will include inspection of treatment records and unannounced inspections of the facility by an inspector, and may include inspection of articles prior to or after irradiation. Facilities that carry out irradiation operations must notify the Director of Preclearance, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1236, of scheduled operations at least 30 days before operations commence, except where otherwise provided in the facility preclearance work plan. To ensure the appropriate level of monitoring, before articles may be imported in accordance with this section, the following agreements must be signed:

(1) *Irradiation treatment framework equivalency work plan.* The plant protection service of a country from which articles are to be imported into the United States in accordance with this section must sign a framework equivalency work plan with APHIS. In this plan, both the foreign plant protection service and APHIS will specify the following items for their respective countries:

(i) Citations for any requirements that apply to the importation of irradiated fruits and vegetables;

(ii) The type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated fruits and vegetables into that country; and

(iii) Any other conditions that must be met to allow the importation of irradiated fruits and vegetables into that country.

(2) *Facility preclearance work plan.* Prior to commencing importation into the United States of articles treated at a foreign irradiation facility, APHIS and the plant protection service of the country from which articles are to be

imported must jointly develop a preclearance work plan that details the activities that APHIS and the foreign plant protection service will carry out in connection with each irradiation facility to verify the facility's compliance with the requirements of this section. Typical activities to be described in this work plan may include frequency of visits to the facility by APHIS and foreign plant protection inspectors, methods for reviewing facility records, and methods for verifying that facilities are in compliance with the requirements for separation of articles, packaging, labeling, and other requirements of this section. This facility preclearance work plan will be reviewed and renewed by APHIS and the foreign plant protection service on an annual basis.

(3) *Trust fund agreement.* Irradiated articles may be imported into the United States in accordance with this section only if the plant protection service of the country in which the irradiation facility is located has entered into a trust fund agreement with APHIS. That agreement requires the plant protection service to pay, in advance of each shipping season, all costs that APHIS estimates it will incur in providing inspection and treatment monitoring services at the irradiation facility during that shipping season. Those costs include administrative expenses and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by APHIS in performing these services. The agreement will describe the general nature and scope of APHIS services provided at irradiation facilities covered by the agreement, such as whether APHIS inspectors will monitor operations continuously or intermittently, and will generally describe the extent of inspections APHIS will perform on articles prior to and after irradiation. The agreement requires the plant protection service to deposit a certified or cashier's check with APHIS for the amount of those costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement further requires the plant protection service to deposit with

APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before any more articles irradiated in that country may be imported into the United States. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the plant protection service or held on account until needed, at the option of the plant protection service.

(g) *Packaging.* Fruits and vegetables that are irradiated in accordance with this section must be packaged in cartons in the following manner:

(1) All fruits and vegetables treated with irradiation must be shipped in the same cartons in which they are treated. Irradiated fruits and vegetables may not be packaged for shipment in a carton with nonirradiated fruits and vegetables.

(2) For all fruits and vegetables irradiated prior to arrival in the United States:

(i) The fruits and vegetables to be irradiated must be packaged either:

(A) In insect-proof cartons that have no openings that will allow the entry of fruit flies. The cartons must be sealed with seals that will visually indicate if the cartons have been opened. The cartons may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the articles in the carton;³ or

(B) In noninsect-proof cartons that are stored immediately after irradiation in a room completely enclosed by walls or screening that completely precludes access by fruit flies. If stored in noninsect-proof cartons in a room that precludes access by fruit flies, prior to leaving the room each pallet of cartons must be completely enclosed in polyethylene, shrink-wrap, or another solid or netting covering that completely precludes access to the cartons by fruit flies.

³If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Oxford Plant Protection Center, 901 Hillsboro Street, Oxford, NC 27565.

(ii) To preserve the identity of treated lots, each pallet-load of cartons containing the fruits and vegetables must be wrapped before leaving the irradiation facility in one of the following ways:

(A) With polyethylene shrink wrap;

(B) With net wrapping; or

(C) With strapping so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap.

(iii) Packaging must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment. Pallets that remain intact as one unit until entry into the United States may have one such label per pallet. Pallets that are broken apart into smaller units prior to or during entry into the United States must have the required label information on each individual carton.

(h) *Dosimetry systems at the irradiation facility.* (1) Dosimetry mapping must indicate the doses needed to ensure that all the commodity will receive the minimum dose prescribed.

(2) Absorbed dose must be measured using an accurate dosimetry system that ensures that the absorbed dose meets or exceeds the absorbed dose required by paragraph (a) of this section (150, 210, 225, 250, or 300 gray, depending on the target species of fruit fly or seed weevil).

(3) When designing the facility's dosimetry system and procedures for its operation, the facility operator must address guidance and principles from American Society for Testing and Materials (ASTM) standards⁴ or an equivalent standard recognized by the Administrator.

(i) *Records.* An irradiation processor must maintain records of each treated lot for 1 year following the treatment date and must make these records available for inspection by an inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except holidays). These records must in-

clude the lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

(j) *Request for certification and inspection of facility.* Persons requesting certification of an irradiation treatment facility must submit the request for approval in writing to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Oxford Plant Protection Center, 901 Hillsboro Street, Oxford, NC 27565. The initial request must identify the owner, location, and radiation source of the facility, and the applicant must supply additional information about the facility construction, treatment protocols, and operations upon request by APHIS if APHIS requires additional information to evaluate the request. Before the Administrator determines whether an irradiation facility is eligible for certification, an inspector will make a personal inspection of the facility to determine whether it complies with the standards of this section.

(k) *Denial and withdrawal of certification.* (1) The Administrator will withdraw the certification of any irradiation treatment facility upon written request from the irradiation processor.

(2) The Administrator will deny or withdraw certification of an irradiation treatment facility when any provision of this section is not met. Before withdrawing or denying certification, the Administrator will inform the irradiation processor in writing of the reasons for the proposed action and provide the irradiation processor with an opportunity to respond. The Administrator will give the irradiation processor an opportunity for a hearing regarding any dispute of a material fact, in accordance with rules of practice that will be adopted for the proceeding. However, the Administrator will suspend certification pending final determination in the proceeding if he or she determines that suspension is necessary to prevent the spread of any dangerous insect. The suspension will be effective upon oral or written notification, whichever is earlier, to the irradiation processor. In the event of oral notification, written confirmation

⁴Designation ISO/ASTM 51261-2002(E), "Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing," American Society for Testing and Materials, *Annual Book of ASTM Standards*.

will be given to the irradiation processor within 10 days of the oral notification. The suspension will continue in effect pending completion of the proceeding and any judicial review of the proceeding.

(1) *Department not responsible for damage.* This treatment is approved to assure quarantine security against the listed fruit flies. From the literature available, the fruits and vegetables authorized for treatment under this section are believed tolerant to the treatment; however, the facility operator and shipper are responsible for determination of tolerance. The Department of Agriculture and its inspectors assume no responsibility for any loss or damage resulting from any treatment prescribed or monitored. Additionally, the Nuclear Regulatory Commission is responsible for ensuring that irradiation facilities are constructed and operated in a safe manner. Further, the Food and Drug Administration is responsible for ensuring that irradiated foods are safe and wholesome for human consumption.

(Approved by the Office of Management and Budget under control number 0579–0155)

PART 318—HAWAIIAN AND TERRITORIAL QUARANTINE NOTICES

Subpart—Hawaiian Fruits and Vegetables

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